

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED,
IPR PHARMACEUTICALS, INC.,
SHIONOGI SEIYAKU KABUSHIKI KAISHA,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No.: 07-805-JJF-LPS

**PLAINTIFFS' REPLY TO DEFENSES AND COUNTERCLAIMS
OF MYLAN PHARMACEUTICALS INC.**

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively “Plaintiffs”), through their undersigned counsel, reply to the Defenses and Counterclaims of Mylan Pharmaceuticals Inc. (“Mylan”) as follows:

DEFENSES

First Defense

The claims of U.S. Patent No. RE 37,314 E (“the ‘314 patent”) are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Patent Code.

Answer: Plaintiffs deny the allegations in the First Defense.

Second Defense

The manufacture, sale, use, offer for sale, or importation of Mylan Pharmaceuticals Inc.’s proposed rosuvastatin product, that is the subject of the its ANDA, would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the ‘314 patent.

Answer: Plaintiffs deny the allegations in the Second Defense.

Third Defense

The Complaint fails to state a claim upon which relief can be granted.

Answer: Plaintiffs deny the allegations in the Third Defense.

Fourth Defense

Any additional defenses or counterclaims that discovery may reveal.

Answer: Plaintiffs deny the allegations in the Fourth Defense.

COUNTERCLAIMS

The Parties

1. Mylan Pharmaceuticals Inc. is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

Answer: Upon information and belief, Plaintiffs admit that Mylan Pharmaceuticals Inc. is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, but are without knowledge and information sufficient to form a belief as to whether Mylan's zip code is 26504 or 26505.

2. AstraZeneca Pharma purports to be a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803 USA.

Answer: Plaintiffs admit the allegations in Paragraph 2.

3. AstraZeneca UK purports to be a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London W1K 1LN, England.

Answer: Plaintiffs admit the allegations in Paragraph 3.

4. IPR purports to be a corporation operating and existing under the laws of Puerto Rico with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729.

Answer: Plaintiffs admit the allegations in Paragraph 4.

5. Shionogi purports to be a corporation operating and existing under the laws of Japan with its principal place of business at 1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045 Japan.

Answer: Plaintiffs admit the allegations in Paragraph 5.

Jurisdiction and Venue

6. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28, U.S.C. § 2201 and 2202.

Answer: Plaintiffs admit that Mylan's counterclaims purport to arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28, U.S.C. § 2201 and 2202, but deny that the counterclaims are valid or sustainable.

7. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Mylan in this District, and/or because Plaintiffs conduct substantial business in this District.

Answer: Plaintiffs admit that this Court has personal jurisdiction over Plaintiffs for purposes of this action only. Plaintiffs deny the remaining allegations in Paragraph 7.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and 1400(b).

Answer: Plaintiffs admit that venue is proper in this jurisdiction for the purposes of this action only. Plaintiffs deny the remaining allegations in Paragraph 8.

Patent-in-Suit

9. On or about August 7, 2001, the U.S. Patent and Trademark Office ("PTO") reissued U.S. Reissued Patent No. RE 37,314 E ("the '314 patent"), entitled "Pyrimidine Derivatives," to Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe.

Answer: Plaintiffs admit the allegations in Paragraph 9, except that "RE 37,314 E" is also designated as "RE 37,314."

10. Plaintiffs purport and claim to own, and to have the right to enforce, the '314 patent.

Answer: Plaintiffs admit the allegations in Paragraph 10.

11. On or about December 11, 2007, Plaintiffs sued Mylan in this District alleging infringement of the '314 patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Plaintiffs admit that they filed a complaint in this District on December 11, 2007, alleging infringement by Mylan of the '314 patent under both 35 U.S.C. §§ 271(e)(2)(A) and 271(a). Plaintiffs deny the remaining allegations in this Paragraph.

Count I
(Declaratory Judgment of Invalidity of the '314 Patent)

12. Mylan re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

Answer: Plaintiffs repeat their responses to each of the foregoing Paragraphs as if fully set forth herein.

13. There is an actual, substantial, and continuing justiciable case or controversy between Mylan and Plaintiffs regarding the invalidity of the '314 patent.

Answer: Plaintiffs admit the allegations in Paragraph 13.

14. The claims of the '314 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

Answer: Plaintiffs deny the allegations in Paragraph 14.

15. Mylan is entitled to a judicial declaration that the claims of the '314 patent are invalid.

Answer: Plaintiffs deny the allegations in Paragraph 15.

Count II
(Declaratory Judgment of Non-Infringement of the '314 Patent)

16. Mylan re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

Answer: Plaintiffs repeat their responses to each of the foregoing Paragraphs as if fully set forth herein.

17. There exists an actual, substantial, and continuing justiciable case or controversy between Mylan and Plaintiffs regarding non-infringement of the '314 patent.

Answer: Plaintiffs admit the allegations in Paragraph 17.

18. The manufacture, use, sale, offer for sale, or importation of the rosuvastatin tablets that are the subject of Mylan's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid claim and/or enforceable claim of the '314 patent.

Answer: Plaintiffs deny the allegations in Paragraph 18.

19. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the rosuvastatin tablets that are the subject of Mylan's ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '314 patent.

Answer: Plaintiffs deny the allegations in Paragraph 19.

* * *

Plaintiffs deny all remaining allegations not specifically admitted herein and deny that Mylan is entitled to any relief requested or any relief at all.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment against Mylan as follows:

- (a) dismissing Mylan's counterclaims with prejudice;
- (b) finding that this is an exceptional case and granting AstraZeneca's reasonable attorney fees pursuant to 35 U.S.C. § 285; and
- (c) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

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Respectfully Submitted:

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Dated: March 21, 2008

CERTIFICATE OF SERVICE

I hereby certify on this 21st day of March, 2008 I electronically filed the foregoing PLAINTIFFS' REPLY TO DEFENSES AND COUNTERCLAIMS OF MYLAN PHARMACEUTICALS INC. with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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The undersigned counsel further certifies that, on March 21, 2008, copies of the foregoing document was also served upon the following individuals in the manner indicated:

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